

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF TRANSMITTAL
OF COPIES OF TRANSLATION
OF THE INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY
(CHAPTER I OR CHAPTER II
OF THE PATENT COOPERATION TREATY)
(PCT Rules 44bis.3(c) and 72.2)

To:

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E 4. JAN. 2007
First:
Patentanwältin

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| Date of mailing (day/month/year) 28 December 2006 (28.12.2006) | |
| Applicant's or agent's file reference 31944P WO/WW | IMPORTANT NOTIFICATION |
| International application No. PCT/EP2005/000215 | International filing date (day/month/year) 12 January 2005 (12.01.2005) |
| Applicant REINMÜLLER, Johannes et al | |

1. Transmittal of the translation to the applicant.

- ☐ The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter I).
- ☒ The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter II).

2. Transmittal of the copy of the translation to the designated or elected Offices.

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following designated or elected Offices requiring such translation:

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The following designated or elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AE, AG, AL, AM, AP, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EA, EC, EE, EG, EP, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OA, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability (Chapter II).

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned within the applicable time limit (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

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| The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland | Authorized officer Ellen Moyse |
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TRANSLATION

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

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|--|---|---|
| Applicant's or agent's file reference 31944P WO/WW | FOR FURTHER ACTION | See Form PCT/IPEA/416 |
| International application No. PCT/EP2005/000215 | International filing date (day/month/year) 12.01.2005 | Priority date (day/month/year) 14.01.2004 |
| International Patent Classification (IPC) or national classification and IPC A61 K31/728, A61 P17/00, A61 P27/02 | | |
| Applicant REINMÜLLER, Johannes | | |

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|----|--|--|
| 1. | This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36. | |
| 2. | This REPORT consists of a total of <u>7</u> sheets, including this cover sheet. | |
| 3. | This report is also accompanied by ANNEXES, comprising: a. <input checked="" type="checkbox"/> (sent to the applicant and to the International Bureau) a total of <u>4</u> sheets, as follows: <input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). <input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions). | |
| 4. | This report contains indications relating to the following items: <input checked="" type="checkbox"/> Box No. I Basis of the report <input type="checkbox"/> Box No. II Priority <input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability <input type="checkbox"/> Box No. IV Lack of unity of invention <input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement <input type="checkbox"/> Box No. VI Certain documents cited <input type="checkbox"/> Box No. VII Certain defects in the international application <input type="checkbox"/> Box No. VIII Certain observations on the international application | |

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|---|-----------------------------------|
| Date of submission of the demand | Date of completion of this report |
| Name and mailing address of the IPEA/EP | Authorized officer |
| Facsimile No. | Telephone No. |

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/EP2005/000215

Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language _____ which is the language of a translation furnished for the purposes of:
- ☐ international search (Rule 12.3 and 23.1(b))
- ☐ publication of the international application (Rule 12.4)
- ☐ international preliminary examination (Rule 55.2 and/or 55.3)
2. With regard to the elements of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):
- ☐ the international application as originally filed/furnished
- ☒ the description:
- pages 1-11 _____ as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☒ the claims:
- nos. _____ as originally filed/furnished
- nos.* _____ as amended (together with any statement) under Article 19
- nos.* 1-21 _____ received by this Authority on 08.08.2005 with letter
- nos.* _____ received by this Authority on of 08.08.2005
- ☐ the drawings:
- sheets _____ as originally filed/furnished
- sheets* _____ received by this Authority on _____
- sheets* _____ received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

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Box No. III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application☒ claims Nos. 14

because:

☒ the said international application, or the said claims Nos. in relation to industrial applicability
relate to the following subject matter which does not require an international preliminary examination (*specify*):

Claim 14 relates to subject matter which, in the opinion of this Authority, falls under PCT Rule 67.1(iv). Consequently, no expert opinion has been established in respect of the industrial applicability of the subject matter of said claim (PCT Article 34(4)(a)(i)).

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.☐ no international search report has been established for said claims Nos. _____☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished☐ does not comply with the standard

the computer readable form

☐ has not been furnished☐ does not comply with the standard☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.☐ See Supplemental Box for further details.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Claims

YES

Claims 1-21

NO

Inventive step (IS)

Claims

YES

Claims 1-21

NO

Industrial applicability (IA)

Claims

1-13, 15-21

YES

Claims

NO

2. Citations and explanations (Rule 70.7)

1. During the proceedings reference will be made to the documents listed in the international search report. The numbering of the documents, D1-D8, follows the sequence in which they appear in the search report. The passages of text cited therein, in particular, are taken into consideration.

2. The application discloses the use of hyaluronic acid in cross-linked form for producing an agent for preventing or treating inflammatory skin diseases or inflammatory diseases of the mucous membrane. Also disclosed is the use of hyaluronic acid in cross-linked form for producing an agent for preventing or treating inflammatory eye diseases.

3. Novelty (PCT Article 33(2))

Document D1 discloses pharmaceutical preparations that contain cross-linked or uncross-linked hyaluronic acid associated with heparin and auxiliary substances for treating wounds, viral

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Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

infections, eye diseases, for example epidemic keratoconjunctivitis, or illnesses affecting the respiratory tract, for example colds and chills (column 5, lines 12-41).

The therapeutic application as per claim 1, "for preventing or treating inflammatory skin diseases or inflammatory diseases of the mucous membrane", also covers viral infections (see page 8, second paragraph of the description). Such a use, however, is already described in D1.

D1 also describes a use for treating keratoconjunctivitis. This use also is covered by claim 5 (see page 10, line 16 of the description).

The subject matter of claims 1-21 thus lacks novelty over D1 (PCT Article 33(2)).

Documents D2-D8 each disclose the use of hyaluronic acid for treating inflammatory diseases. None of the documents, however, discloses the use of hyaluronic acid in cross-linked form.

5. Inventive step (PCT Article 33(3))

The application addresses the problem of providing an agent for preventing or treating inflammatory skin diseases or inflammatory diseases of the mucous membrane.

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Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

This is solved by the use of hyaluronic acid in cross-linked form to produce such an agent.

The use of hyaluronic acid for treating inflammatory diseases is known in the art. Individually, the documents concern the following diseases:

- D1: keratoconjunctivitis and viral infections, in particular herpes;
- D2: diseases of the rectal mucosal, in particular pruritus ani, herpes and ulcer;
- D3: acne, psoriasis and chronic eczema;
- D4: contact dermatitis, eczema, lichen and psoriasis;
- D5: wounds, reduction of inflammation;
- D6: burns and scalds;
- D7: acne
- D8: genital warts and psoriasis

As can be seen from the description of the prior art, the use of hyaluronic acid for treating inflammatory skin diseases or inflammatory diseases of the mucous membrane and inflammatory eye diseases has long been known.

Also, the use of specific hyaluronic acids (short-chained, long-chained, cross-linked or uncross-linked) and the manner of application (intradermal, topical) appears obvious to a person skilled in the art for optimising treatment.

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Box No. V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement

If the use of hyaluronic acid in cross-linked form in contrast to uncross-linked hyaluronic acid has a surprising effect, for example an improved therapeutic effect, then that effect should be demonstrated by means of comparative tests which make a comparison with the prior art.

Consequently, an inventive step cannot currently be acknowledged in respect of the subject matter of claims 1-21 (PCT Article 33(3)).